

NDA 7-409/S-039
NDA 8-370/S-028
NDA 7-961/S-025

AUG 17 1999

Hoechst Marion Roussel
Attention: Kim Leitzke
10236 Marion Park Drive, P.O. Box 9627
Kansas City, MO 64134

Dear Ms. Leitzke:

Please refer to your supplemental new drug applications dated April 2, 1999, received April 5, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bentyt (dicyclomine hydrochloride USP) Tablets/Capsules, Injection, and Syrup.

We note that these supplements were submitted as 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

These supplemental new drug applications provide for the revision of the **OVERDOSAGE** section of the package insert to include a description of a 15 Day adverse event report in which a 37 year old female reported numbness, cold fingertips, abdominal pain, decreased appetite, dry mouth, and nervousness following the ingestion of 320 mg daily for several days. Your submission stated March 18, 1999 as the implementation date for the change.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the final printed labeling submitted April 2, 1999. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 -Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR314.80 and 314.81.

If you have any questions, contact Alice Kacuba, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.

Director

Division of Gastrointestinal

and Coagulation Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research